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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
P.O. Box 3012
Bothell, WA 98041-3012

Telephone: 206-486-8788
FAX: 206-483-4996

April 18, 1997

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 97-17

Simon R. McKenzie
President/Chief Executive Officer
Bartels, Inc.
2005 NW Sammamish Road, Suite 107
Issaquah, WA 98027

WARNING LETTER

Dear Mr. McKenzie:

During an inspection of your manufacturing facility conducted between March 24 and March 28, 1997, our investigators collected information that revealed a serious regulatory problem involving the cell culture, in-vitro diagnostics, and transport products which are made and marketed by your firm.

Our inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

Failure to have in place an adequate organizational structure and sufficient personnel to assure that the devices are manufactured in accordance with the GMP requirements (820.20).

Failure to establish a quality assurance program consisting of procedures adequate to assure approval or rejection of all components, manufacturing materials, in-process materials, labeling, and finished devices [820.20(a)(2)].

Failure to perform planned and periodic audits of the quality assurance program in accordance with written procedures [820.20(b)].

Failure to control environmental conditions to prevent contamination of the devices and to provide proper conditions for operations [820.46].

Failure to provide written procedure for acceptance of components. Components are not inspected, sampled, and tested for conformance to specifications [820.80].

Failure to establish and implement written manufacturing specifications and processing procedures to assure that the device conforms to its original design [820.100].

Failure to establish and implement control procedures to assure that the reprocessed device meets the original specification [820.115].

Failure to review and evaluate complaints involving the possible failure of devices [820.198(b)].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. At the conclusion of the inspection, the list of observations (FDA 483) was presented to and discussed with you. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking

to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Direct your response to Thomas S. Piekarski, Compliance Officer, Food and Drug Administration, P.O. Box 3012, Bothell, WA 98041-3012.

Sincerely,

Roger L. Lowell
District Director